IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACADIA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
HETERO LABS LIMITED,	)	
HETERO LABS LIMITED UNIT-V, and	)	
HETERO USA INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff ACADIA Pharmaceuticals Inc. ("ACADIA" or "Plaintiff"), for its Complaint against Defendants Hetero Labs Limited ("Hetero Labs"), Hetero Labs Limited Unit-V ("Hetero Unit-V"), and Hetero USA Inc. ("Hetero USA") (collectively, "Hetero" or "Defendants"), hereby alleges as follows:

THE PARTIES

1. ACADIA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3611 Valley Centre Drive Suite 300, San Diego, California 92130.

2. Upon information and belief, Hetero Labs is an entity organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate, Industrial Estate, Sanath Nagar, Hyderabad 500018, Telangana, India.

3. Upon information and belief, Hetero Unit-V is an entity organized and existing under the laws of India, with its principal place of business at Polepally, Jadcherla, Mahabub Nagar 509301, Andhra Pradesh, India.

4. Upon information and belief, Hetero USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

5. Upon information and belief, Hetero USA is the U.S. Regulatory Agent for Hetero Unit-V, which is a division of Hetero Labs.

6. Upon information and belief, Hetero USA is a subsidiary of Hetero Labs.

7. Upon information and belief, Hetero USA acts at the direction, and for the benefit, of Hetero Labs and is controlled and/or dominated by Hetero Labs.

8. Upon information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA work in concert, either directly or indirectly, with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in the State of Delaware.

9. Upon information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA have participated and collaborated in the preparation, filing, and seeking FDA approval of Abbreviated New Drug Application ("ANDA") No. 214828 for Pimavanserin Tartrate Capsules, Eq 34 mg base ("the Hetero Generic Product"); continue to participate and collaborate in seeking FDA approval of ANDA No. 214828; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and/or sale of the Hetero Generic Product throughout the United States including in the State of Delaware.

NATURE OF THE ACTION

10. This is a civil action for infringement of United States Patent Nos. 7,601,740 ("the '740 patent"), 10,449,185 ("the '185 patent"), and 10,646,480 ("the '480 patent") (collectively "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

JURISDICTION & VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 2201, 2202, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

12. Upon information and belief, Hetero USA is a Delaware corporation and has a registered agent in the State of Delaware, W/K Incorporating Services, Inc., located at 3500 South DuPont Highway, Dover, Delaware 19901.

13. Venue is proper in this Court as to Hetero USA under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because Hetero USA is incorporated in Delaware and thus resides in this Judicial District. Hetero USA has also committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

14. This Court has personal jurisdiction over Hetero USA, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, Hetero USA is a Delaware corporation and thus resides in Delaware and has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware. Hetero USA has indicated that it intends to engage in the commercial manufacture, use, or sale of the Hetero Generic Product under ANDA No. 214828 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

15. Upon information and belief, Hetero USA has purposely availed itself of the privilege of doing business in Delaware, including by, *inter alia*, manufacturing and selling generic

pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates.

16. This Court also has personal jurisdiction over Hetero USA, and venue is proper in this Judicial District, by virtue of the fact that, upon information and belief, Hetero USA maintains pervasive, continuous, and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of Delaware, through its own actions and through the actions of its agents and affiliates.

17. Venue is proper in this Court as to Hetero Labs under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, Hetero Labs, directly or indirectly through its subsidiaries, agents, and/or alter egos, has a regular and established place of business in the State of Delaware, including, at least, Hetero USA, a subsidiary incorporated in the State of Delaware, and has also committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

18. This Court has personal jurisdiction over Hetero Labs, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, Hetero Labs owns a subsidiary that is incorporated in the State of Delaware and has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware. Hetero Labs has indicated that it intends, directly or indirectly through its subsidiaries, agents, and/or alter egos, to engage in the commercial manufacture, use, or sale of the Hetero Generic Product under ANDA No. 214828 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

19. Upon information and belief, Hetero Labs has purposely availed itself of the privilege of doing business in Delaware, including by, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, Hetero USA.

20. Hetero's website states that "Hetero has a strong global presence in over 126 countries and focusses on making affordable medicines accessible to patients worldwide." Profile, https://www.heteroworld.com/company-profile.php (last accessed July 23, 2020). Additionally, "Hetero has over 36 advanced manufacturing facilities strategically located across the world – including India, USA, China, Russia, Egypt, Mexico, and Indonesia." Manufacturing Capabilities, https://www.heteroworld.com/manufacturing.php (last accessed July 23, 2020). Hetero describes itself as "one of the largest exporter[s] of therapeutic drugs to a diverse number of markets in . . . America." Products, https://www.heteroworld.com/products.php (last accessed July 23, 2020).

21. This Court also has personal jurisdiction over Hetero Labs, and venue is proper in this Judicial District, by virtue of the fact that, upon information and belief, Hetero Labs, maintains pervasive, continuous, and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of Delaware, through its own actions and through the actions of its agents and affiliates, including, at least, Hetero USA. Upon information and belief, Hetero Labs derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in the State of Delaware.

22. Venue is proper in this Court as to Hetero Unit-V under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, Hetero Unit-V has committed and will commit further acts

of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

23. This Court has personal jurisdiction over Hetero Unit-V, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, Hetero Unit-V: (1) has purposely availed itself of the privilege of doing business in the State of Delaware, including by, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates; and (2) contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware. Hetero Unit-V has indicated that it intends, directly or indirectly through its subsidiaries, agents, and/or alter egos, to engage in the commercial manufacture, use, or sale of the Hetero Generic Product under ANDA No. 214828 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

24. This Court also has personal jurisdiction over Hetero Unit-V, and venue is proper in this Judicial District, by virtue of the fact that, upon information and belief, Hetero Unit-V, maintains pervasive, continuous, and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of Delaware, through its own actions and through the actions of its agents and affiliates. Upon information and belief, Hetero Unit-V derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in the State of Delaware.

25. Hetero's infringing actions with respect to the filing of ANDA No. 214828 and intent to commercialize the Hetero Generic Product have led and/or will lead to foreseeable harm and injury to ACADIA.

26. This Court also has personal jurisdiction over Hetero USA, Hetero Labs, and Hetero Unit-V, and venue is proper in this Court because, *inter alia*, they have previously been sued together in this Judicial District and have not challenged personal jurisdiction or venue, and have purposefully availed themselves of the rights and benefits of the jurisdiction of this Court by filing counterclaims in this Judicial District. *See*, *e.g.*, *Bial-Portela & CA S.A. v. Hetero Labs Ltd.*, C.A. No. 20-0780-CFC (D. Del.) (Hetero Labs, Hetero Unit-V and Hetero USA did not contest jurisdiction); *Otsuka Pharm. Co., Ltd. v. Hetero Labs Ltd.*, C.A. No. 19-1954-LPS (D. Del.) (same); *Pfizer Inc. v. Hetero USA Inc.*, C.A. No. 19-0751-CFC (D. Del.) (same); *Genentech, Inc. v. Hetero Labs Ltd.*, C.A. No. 19-178-RGA (D. Del.) (Hetero Labs, Hetero Unit-V and Hetero USA did not contest jurisdiction and Hetero USA filed counterclaims).

27. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Hetero Labs and Hetero Unit-V in this action, this Court may exercise jurisdiction over Hetero Labs and Hetero Unit-V pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) ACADIA's claims arise under federal law; (b) Hetero Labs and Hetero Unit-V are foreign defendants not subject to personal jurisdiction in the courts of any state; and (c) Hetero Labs and Hetero Unit-V have sufficient contacts with the United States as a whole, including but not limited to submitting various ANDAs to the FDA, and manufacturing and selling active pharmaceutical ingredients that are used in the products distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs and Hetero Unit-V satisfies due process.

ACADIA'S NDA AND THE PATENTS-IN-SUIT

28. ACADIA holds New Drug Application ("NDA") No. 210793 for oral capsules containing pimavanserin tartrate, Eq. 34 mg base as the active ingredient. ACADIA exclusively manufactures, markets, and sells these oral capsules in the United States under the brand name NUPLAZID®.

29. On October 13, 2009, the '740 patent, entitled "Selective serotonin 2A/2C receptor inverse agonists as therapeutics for neurodegenerative diseases" was duly and legally issued. A copy of the '740 patent is attached as Exhibit A.

30. ACADIA owns the '740 patent.

31. On October 22, 2019, the '185 patent, entitled "Formulations of pimavanserin" was duly and legally issued. A copy of the '185 patent is attached as Exhibit B.

32. ACADIA owns the '185 patent.

33. On May 12, 2020, the '480 patent, entitled "Formulations of pimavanserin" was duly and legally issued. A copy of the '480 patent is attached as Exhibit C.

34. ACADIA owns the '480 patent.

35. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering NUPLAZID® or its use.

HETERO'S ANDA AND PARAGRAPH IV NOTIFICATION

36. Upon information and belief, Hetero submitted ANDA No. 214828 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Hetero's ANDA No. 214828 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the Hetero Generic Product prior to the expiration of the patents-in-suit.

37. Upon information and belief, by filing ANDA No. 214828, Hetero has certified to the FDA that the Hetero Generic Product has the same active ingredient as NUPLAZID® and the same or substantially the same proposed labeling as NUPLAZID®.

38. ACADIA received written notifications of Hetero's ANDA No. 214828 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated June 25, 2020 ("Hetero's Notice Letter").

39. Hetero's Notice Letter represents that Hetero certified in ANDA No. 214828 that the claims of the patent-in-suit are invalid or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Hetero Generic Product.

40. According to applicable regulations, Notice Letters such as Hetero's Notice Letter must contain a detailed statement of the factual and legal bases for the applicant's opinion that the patent is invalid, unenforceable, or not infringed, which includes a claim-by-claim analysis, describing "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

41. For at least one claim of the '740 patent, Hetero's Notice Letter failed to provide a claim-by-claim analysis on the full and detailed explanation of the grounds supporting Hetero's opinion that the claims of the '740 patent are alleged to be invalid.

42. This action is being commenced by ACADIA within 45 days of its receipt of Hetero's Notice Letter.

43. Hetero's Notice Letter contained an Offer of Confidential Access ("OCA") to certain confidential information regarding the Hetero Generic Product. ACADIA and Hetero

subsequently exchanged markups of the OCA in an attempt to reach agreement on the terms for confidential access. As of the filing of this Complaint, however, the parties have not been able to reach an agreement.

44. To date, Hetero has not provided ACADIA with a copy of any portions of ANDA No. 214828 or any information regarding the Hetero Generic Product, beyond the information set forth in Hetero's Notice Letter.

45. The limited information relating to the Hetero Generic Product that was provided in Hetero's Notice Letter does not demonstrate that the Hetero Generic Product, which Hetero has asked the FDA to approve for sale in the United States, will not fall within the scope of issued claims of the patents-in-suit.

COUNT I – INFRINGEMENT BY
HETERO LABS, HETERO UNIT-V, AND HETERO USA

46. ACADIA re-alleges paragraphs 1-45 as if fully set forth herein.

47. Hetero's submission of ANDA No. 214828 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A).

48. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Hetero certified in ANDA No. 214828 that the claims of the patents-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Hetero Generic Product. Hetero notified ACADIA of that certification and provided a statement of the alleged bases for its claims.

49. Hetero's Notice Letter do not identify any factual basis for, or any opinion of, invalidity regarding claims 2-10, 24 and 25 of the '740 patent.

50. Separate and apart from certain contentions regarding patent validity, Hetero's Notice Letter does not identify any factual basis for, or any opinion of, noninfringement of claims 1, 11-23 and 26 of the '740 patent or the claims of the '480 patent.

51. Defendants are jointly and severally liable for infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214828 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the Hetero Generic Product prior to the expiration of the patents-in-suit.

52. Upon information and belief, Hetero was aware of the existence of the patents-in-suit and was aware that the filing of ANDA No. 214828 and certification with respect to the patents-in-suit constituted an act of infringement of those patents.

53. Hetero filed ANDA No. 214828 without adequate justification for asserting that the patents-in-suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Hetero Generic Product.

54. Moreover, if Hetero manufactures, uses, offers for sale, or imports into the United States any of the Hetero Generic Product, or induces or contributes to any such conduct, prior to the expiration of the patents-in-suit, including any applicable exclusivities or extensions, it would infringe one or more claims of those patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

55. ACADIA is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Hetero's ANDA No. 214828 be a date that is not earlier than the expiration of the patents-in-suit, or any later expiration of exclusivity for the patents-in-suit to which ACADIA is or becomes entitled.

56. ACADIA will be irreparably harmed by Hetero's infringing activities unless those activities are enjoined by this Court. ACADIA does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, ACADIA requests that the Court grant the following relief:

A. A Judgement be entered that Hetero has infringed the '740 patent, the '185 patent, and the '480 patent by submitting ANDA No. 214828 to the FDA;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Hetero's ANDA No. 214828 will not be earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which ACADIA is or becomes entitled;

C. An Order permanently enjoining Hetero, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with Hetero, from commercially manufacturing, using, offering to sell, selling, marketing, distribution, or importing the Hetero Generic Product identified in this Complaint, or any product that infringes or induces or contributes to the infringement of one or more of the patents-in-suit, prior to the expiration of the patents-in-suit, including any exclusivities or extensions to which ACADIA is or becomes entitled;

D. That ACADIA be awarded monetary relief to the extent Hetero commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any product that infringes or induces or contributes to the infringement of the patents-in-suit, within the United States prior to the expiration of the patents-in-suit, including any later expiration of any patent term extensions or exclusivities for the patents-in-suit to which ACADIA is or will become entitled, and that any such monetary relief be awarded to ACADIA with prejudgment interest;

E. A finding that this case is an exceptional case and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. That ACADIA be awarded the costs and expenses that it incurs in prosecuting this action; and

G. Such other and further relief as this Court may deem just and proper.

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